

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

FOREST LABORATORIES, INC., FOREST	)	
LABORATORIES HOLDINGS, LTD., and	)	
MERZ PHARMA GMBH & CO. KGAA,	)	
MERZ PHARMACEUTICALS GMBH,	)	
	)	
Plaintiffs,	)	C.A. No. 08-22-GMS
	)	
v.	)	
	)	
PLIVA D.D., PLIVA-HRVATSKA D.O.O.,	)	
BARR LABORATORIES, INC. and	)	
BARR PHARMACEUTICALS, INC.,	)	
	)	
Defendants.	)	

**ANSWER BY DEFENDANT PLIVA D.D.**

Defendant PLIVA d.d. ("Defendant") answers the Amended Complaint of Forest Laboratories, Inc., Forest Laboratories Holdings, Ltd. (together with Forest Laboratories, Inc. "Forest"), Merz Pharma GmbH & Co. KGaA and Merz Pharmaceuticals GmbH (together with Merz Pharma GmbH & Co. KgaA, "Merz") (collectively "Plaintiffs"), as follows:

1. Upon information and belief, based on the allegations of the Amended Complaint, Defendant admits that Forest Laboratories, Inc. is a Delaware corporation having a principal place of business at 909 Third Avenue, New York, New York 10022. Defendant otherwise denies the allegations of paragraph 1 of the Amended Complaint.

2. Upon information and belief, based on the allegations of the Amended Complaint, Defendant admits Forest Laboratories Holdings, Ltd. is an Irish corporation having offices at Milner House, 18 Parliament Street, Hamilton JM11, Bermuda. Defendant otherwise denies the allegations of paragraph 2 of the Amended Complaint.

3. Upon information and belief, based on the allegations of the Amended Complaint, Defendant admits Merz Pharma GmbH & Co. KgaA is a German corporation having a principal place of business at Eckenheimer Landstraße 100, D-60318 Frankfurt am Main, Germany. Defendant otherwise denies the allegations of paragraph 3 of the Amended Complaint.

4. Upon information and belief, based on the allegations of the Amended Complaint, Defendant admits Merz Pharmaceuticals GmbH is a German corporation having a principal place of business at Eckenheimer Landstraße 100, D-60318 Frankfurt am Main, Germany. Defendant otherwise denies the allegations of paragraph 4 of the Amended Complaint.

5. Defendant admits that it is a Croatian corporation having a principal place of business at Ulica grada Vukovara 49, 10000 Zagreb, Croatia. However, Defendant denies that it has been properly served with the Summons and Amended Complaint.

6. Upon information and belief, based on the allegations of the Amended Complaint, Defendant admits that PLIVA-Hrvatska d.o.o. is a Croatian corporation having a principal place of business at Ulica grada Vukovara 49, 10000 Zagreb, Croatia.

7. Upon information and belief, based on the allegations of the Amended Complaint, Defendant admits that Barr Laboratories is a Delaware corporation with a place of business at 233 Quaker Road, Pomona, New York 10970. Defendant otherwise denies the allegations of paragraph 7 of the Amended Complaint.

8. Defendant denies the allegations of paragraph 8 of the Amended Complaint.

9. Defendant admits that, at present, Barr Pharmaceuticals, Inc. and PLIVA d.d. have at least one officer and one director in common, but denies that they have all officers and

directors in common. Defendant otherwise denies the allegations of paragraph 9 of the Amended Complaint.

10. Defendant admits that PLIVA-Hrvatska d.o.o. is a wholly-owned subsidiary of PLIVA d.d. Defendant otherwise denies the allegations of paragraph 10 of the Amended Complaint.

11. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 11 of the Amended Complaint, and therefore denies them.

12. Defendant denies the allegations of paragraph 12 of the Amended Complaint.

13. Defendant denies the allegations of paragraph 13 of the Amended Complaint.

14. The allegations of paragraph 14 of the Amended Complaint state a legal conclusion to which no response is required. Defendant admits that Plaintiffs purport to state a claim for infringement of United States Patent No. 5,061,703 ("the '703 patent") under the patent laws of the United States, arising under 35 U.S.C. § 271(e)(2)(A), 271(a), (b) and/or (c). Defendant denies the remaining allegations of paragraph 14 of the Amended Complaint.

15. The allegations of paragraph 15 of the Amended Complaint state a legal conclusion to which no response is required. Defendant admits that Plaintiffs purport to base subject matter jurisdiction on 28 U.S.C. §§ 1331 and 1338(a). Defendant denies the remaining allegations of paragraph 15 of the Amended Complaint.

16. Defendant denies that PLIVA d.d. and PLIVA-Hrvatska d.o.o. have any presence in Delaware, or any systematic and continuous contacts with Delaware, and further denies that

this Court has personal jurisdiction over PLIVA d.d. and PLIVA-Hrvatska d.o.o. for the reasons alleged in paragraph 16 of the Amended Complaint. Defendant denies the remaining allegations of paragraph 16 of the Amended Complaint. In addition, Defendant denies that PLIVA d.d. has been properly served.

17. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 17 of the Amended Complaint, and therefore denies them.

18. Defendant admits that the face of the '703 patent, titled "Adamantane Derivatives in the Prevention and Treatment of Cerebral Ischemia," states that it was issued by the United States Patent and Trademark Office ("USPTO") on October 29, 1991. Defendant lacks knowledge or information sufficient to form a belief as to the remaining allegations of paragraph 18 of the Amended Complaint, and therefore denies them.

19. Defendant admits that the '703 patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") for Namenda. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 19 of the Amended Complaint, and therefore denies them.

20. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 20 of the Amended Complaint, and therefore denies them.

21. Defendant admits that USPTO records indicate that on August 18, 2004, Merz submitted a request to the USPTO for reexamination of the '703 patent. Defendant admits that USPTO records indicate that the USPTO issued a reexamination certificate for the '703 patent on

November 7, 2006. Defendant lacks knowledge sufficient to form a belief as to the truth of the remaining allegations of paragraph 21 of the Amended Complaint, and therefore denies them.

22. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 22 of the Amended Complaint, and therefore denies them.

23. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 23 of the Amended Complaint, and therefore denies them.

24. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 24 of the Amended Complaint, and therefore denies them.

25. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 25 of the Amended Complaint, and therefore denies them.

26. Defendant denies the allegations of paragraph 26 of the Amended Complaint.

27. Defendant denies the allegations of paragraph 27 of the Amended Complaint.

## **DEFENSES**

### **FIRST DEFENSE (Lack of Personal Jurisdiction)**

28. The Court lacks personal jurisdiction over Defendant Pliva d.d.

### **SECOND DEFENSE (Insufficient Service of Process)**

29. Plaintiffs have not properly served process upon Defendant Pliva d.d.

**THIRD DEFENSE**  
**(Noninfringement)**

30. The manufacture, use, or sale, of memantine hydrochloride pursuant to ANDA No. 90-045 will not infringe any valid, enforceable claim of the '703 patent.

**FOURTH DEFENSE**  
**(Invalidity)**

31. The claims of the '703 patent are invalid for failure to comply with one or more of the conditions for patentability as specified in Title 35 U.S.C. §§ 1 *et seq.*

**FIFTH DEFENSE**  
**(Improper Broadening Reexamination)**

32. If any of the claims of the '703 patent are construed to cover the manufacture, use or sale of memantine hydrochloride pursuant to ANDA No. 90-045, those claims of the '703 patent are invalid for failure to comply with the conditions for patentability as specified in Title 35 U.S.C. § 305.

**SIXTH DEFENSE**  
**(Failure to State a Claim Upon Which Relief Can be Granted)**

33. The Amended Complaint fails to state a claim against Pliva d.d. upon which relief may be granted.

**PRAYER FOR RELIEF**

WHEREFORE, Defendant prays that the Court enter judgment against Plaintiffs:

- A. Denying all relief sought in the Amended Complaint, and dismissing the complaint with prejudice;
- B. Enjoining Plaintiffs, their assigns, and all those in privity therewith from asserting the '703 patent against Defendant or any of its customers or suppliers;
- C. Awarding Defendant its attorneys' fees pursuant to 35 U.S.C. § 285, and its costs and expenses; and
- D. Awarding Defendant such other and further relief as may be just and proper.

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Dated: March 3, 2008  
852441 / 32643

*Attorneys for Defendants PLIVA d.d., PLIVA-Hrvatska d.o.o., Barr Laboratories, Inc. and Barr Pharmaceuticals, Inc.*

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

**CERTIFICATE OF SERVICE**

I, David E. Moore, hereby certify that on March 3, 2008, the attached document was electronically filed with the Clerk of the Court using CM/ECF which will send notification to the registered attorney(s) of record that the document has been filed and is available for viewing and downloading.

I hereby certify that on March 3, 2008, I have Electronically Mailed the document to the following person(s)

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